IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Appellant	:	NOLTING, John		
Filed	:	April 25, 2006		
TC/A.U.	:	1615		
Examiner	:	HELM, Caralynne E.		
Docket No.	:	P1394		
Customer No.	:	28390		
Title	:	**COATED STENT WITH TIMED RELEASE OF MULTIPLE THERAPEUTIC AGENTS TO INHIBIT RESTENOSIS ADJACENT TO THE STENT ENDS**		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

APPEAL BRIEF

Dear Sir:

Please consider Appellant's brief as follows:

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1. REAL PARTY IN INTEREST

The real party in interest is Assignee Medtronic Vascular, Inc., a corporation having an office and a place of business at 3576 Unocal Place, Santa Rosa, California 95403.

2. RELATED APPEALS AND INTERFERENCES

Appellant and the undersigned attorneys are not aware of any appeals, judicial proceedings, or any interferences which may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1-3, 7-12, 14, 15, and 18-32 are pending.

Claims 30-32 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Claims 12, 14, 15, and 18-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0153983 to Miller, *et al.* (the *Miller* publication) in view of U.S. Patent No. 6,471,980 to Sirhan, *et al.* (the *Sirhan C* patent).

Claims 1-3, 7-12, and 19-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2003/0033007 to Sirhan, *et al.* (the *Sirhan B* publication) in view of U.S. Patent Publication No. 2004/0002755 to Fischell, *et al.* (the *Fischell* publication).

Claims 12 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2004/0249449 to Shanley, *et al.* (the *Shanley* publication).

Claims 1, 23, 30, and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of the *Sirhan B* publication in view of the *Fischell* publication and further in view of the *Shanley* publication.

Claims 1-3, 7-12, 14, 15, and 18-32 are the claims on appeal. *See* Claims Appendix.

4. STATUS OF AMENDMENTS

No amendments to the claims were entered subsequent to the final Office Action mailed on April 29, 2010.

5. SUMMARY OF CLAIMED SUBJECT MATTER

In this Summary of Claimed Subject Matter, all citations are to the specification of United States Patent Application 11/563,785. All citations are illustrative only and additional support for the cited element may be found elsewhere in the specification. *See* paragraph [0015] - [0042]; specification: page 4, line 7 - page 10, line 27. Specific citations below include both the paragraph number in the published application and the page/line number in the application as filed.

Independent Claim 1:

A system for treating a vascular condition, comprising:

a catheter (Figure 1, element 110; paragraph [0015]-[0017]; specification: page 4, line 7-26); and

a coated stent (Figure 1: element 120; Figure 2: element 200; paragraph [0015]-[0026], [0031]; specification: page 4, line 7 - page 7, line 18; page 8, line 17-25) operably coupled to the catheter, the coated stent including a plurality of therapeutic coatings (Figure 1: elements 132, 134, and 136; Figure 2: elements 222, 224, and 226; paragraph [0015]-[0025], [0031], [0032]; specification: page 4, line 7 - page 7, line 11; page 8, line 17-30); disposed on a distal end (Figure 1: element 124; Figure 2: element 214; paragraph [0015], [0022]; specification: page 4, line 7-18; page 6, line 6-17) and a proximal end (Figure 1: element 122; Figure 2: element 212; paragraph [0015], [0022]; specification: page 4, line 7-18; page 6, line 6-17) of the stent and a plurality of timing coatings (Figure 1: elements 142, 144, and 146; Figure 2: elements 232, 234, and 236; paragraph [0015], [0019], [0022], [0025]; specification: page 4, line 7-18; page 5, line 9-19; page 6, line 6-17; page 7, line 3-11) disposed on the distal and proximal ends of the stent, the timing coatings alternating with the therapeutic coatings, wherein each therapeutic coating comprises a bioerodable polymer and a therapeutic agent and wherein each timing coating comprises a bioerodable polymer, wherein each of the plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the therapeutic coatings being released exclusively and sequentially upon the erosion of

the overlying timing coating without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent.

Dependent Claim 7:

The system of claim 1 wherein each timing coating prevents release of the therapeutic agent from the therapeutic coating positioned beneath the timing coating until a predetermined time (paragraph [0019], [0025]; specification: page 5, line 9-19; page 7, line 3-11).

Dependent Claim 9:

The system of claim 8 further comprising:

at least one timing coating disposed on the longitudinal mid-portion (Figure 1: element 126; Figure 2: element 216; paragraph [0015], [0021], [0022], [0031]; specification: page 4, line 7-18; page 5, line 30 - page 6, line 17; page 8, line 17-25) of the stent.

Dependent Claim 30:

The system of claim 1 wherein each of the plurality of therapeutic agents is released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded (Figure 3; paragraph [0026]-[0033], [0038], [0040]; specification: page 7, line 12 - page 8, line 32; page 9, line 24-31; page 10, line 7-15).

Independent Claim 12:

A coated stent, comprising:

a stent framework (Figure 2: element 210; paragraph [0022]-[0026]; specification: page 6, line 6 - page 7, line 18);

a plurality of therapeutic coatings (Figure 1: elements 132, 134, and 136; Figure 2: elements 222, 224, and 226; paragraph [0015]-[0025], [0031], [0032]; specification: page 4, line 7 - page 7, line 11; page 8, line 17-30) disposed on a distal end (Figure 1: element 124; Figure 2: element 214; paragraph [0015], [0022]; specification: page 4, line 7-18; page 6, line 6-17) and a proximal end (Figure 1: element 122; Figure 2: element 212;

paragraph [0015], [0022]; specification: page 4, line 7-18; page 6, line 6-17) of the stent framework, each therapeutic coating comprising a bioerodable polymer and a therapeutic agent; and

a timing coatings (Figure 1: elements 142, 144, and 146; Figure 2: elements 232, 234, and 236; paragraph [0015], [0019], [0022], [0025]; specification: page 4, line 7-18; page 5, line 9-19; page 6, line 6-17; page 7, line 3-11) disposed on the distal and proximal ends of the stent framework, the timing coatings alternating with the therapeutic coatings, each timing coating comprising a bioerodable polymer,

wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent.

Dependent Claim 18:

The coated stent of claim 12 wherein each timing coating prevents release of the therapeutic agent from the therapeutic coating positioned beneath the timing coating until a predetermined time (paragraph [0019], [0025]; specification: page 5, line 9-19; page 7, line 3-11).

Dependent Claim 20:

The coated stent of claim 19 further comprising:

at least one timing coating disposed on the longitudinal mid-portion (Figure 1: element 126; Figure 2: element 216; paragraph [0015], [0021], [0022], [0031]; specification: page 4, line 7-18; page 5, line 30 - page 6, line 17; page 8, line 17-25) of the stent framework.

Dependent Claim 31:

The coated stent of claim 12 wherein each of the plurality of therapeutic agents is released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded (Figure 3; paragraph [0026]-[0033], [0038], [0040]; specification: page 7, line 12 - page 8, line 32; page 9, line 24-31; page 10, line 7-15).

Independent Claim 23:

A method of inhibiting restenosis adjacent to the ends of a stent used to treat a vascular condition, comprising:

providing a coated stent (Figure 4: element 410; paragraph [0035]; specification: page 9, line 5-11), the coated stent including a first and a second therapeutic coating disposed on a distal and a proximal end of the stent, the first therapeutic coating including a bioerodable polymer and a first therapeutic agent, the second therapeutic coating including a second therapeutic agent, the coated stent further including a first timing coating positioned between the first and second therapeutic coatings, the timing coating comprising a bioerodable polymer;

deploying the coated stent in a vessel (Figure 4: element 420; paragraph [0036]; specification: page 9, line 12-15);

releasing the first therapeutic agent from the first therapeutic coating (Figure 4: element 430; paragraph [0037]; specification: page 9, line 16-23) without releasing the second therapeutic agent from the second therapeutic coating;

eroding the bioerodable polymer of the first therapeutic coating;

actuating the first timing coating (Figure 4: element 440; paragraph [0038]; specification: page 9, line 24-31) based on the eroding of the bioerodable polymer; and

releasing the second therapeutic agent from the second therapeutic coating at a time controlled by the first timing coating (Figure 4: element 450; paragraph [0038]; specification: page 9, line 24-31).

Dependent Claim 27:

The method of claim 26 further comprising:

first actuating a second timing coating, the second timing coating disposed over the third therapeutic agent on the longitudinal mid-portion of the stent framework (Figure 4: element 460; paragraph [0040]; specification: page 10, line 7-15).

Dependent Claim 32:

The method of claim 23 wherein the releasing the second therapeutic agent from the second therapeutic coating comprises releasing the second therapeutic agent from the second

therapeutic coating after the first timing coating has completely eroded (Figure 3; paragraph [0026]-[0033], [0038], [0040]; specification: page 7, line 12 - page 8, line 32; page 9, line 24-31; page 10, line 7-15).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 30-32 failing to comply with the written description requirement under 35 U.S.C. §112, first paragraph.

Whether claims 12, 14, 15, and 18-20 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent Publication No. 2003/0153983 to Miller, *et al*. (the *Miller* publication) in view of U.S. Patent No. 6,471,980 to Sirhan, *et al*. (the *Sirhan C* patent).

Whether claims 1-3, 7-12, and 19-29 are unpatentable under 35 U.S.C. §103(a) over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2003/0033007 to Sirhan, *et al*. (the *Sirhan B* publication) in view of U.S. Patent Publication No. 2004/0002755 to Fischell, *et al.* (the *Fischell* publication).

Whether claims 12 and 31 are unpatentable under 35 U.S.C. §103(a) over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2004/0249449 to Shanley, *et al*. (the *Shanley* publication).

Whether claims 1, 23, 30, and 32 are unpatentable under 35 U.S.C. §103(a) over the *Miller* publication in view of the *Sirhan C* patent and further in view of the *Sirhan B* publication in view of the *Fischell* publication and further in view of the *Shanley* publication.

7. ARGUMENTS

The Appellant respectfully submits that claims 1-3, 7-12, 14, 15, and 18-32 are allowable over the cited references under 35 U.S.C. §103(a), and that the rejection of claims 1-3, 7-12, 14, 15, and 18-32 should be reversed. The Appellant further respectfully submits that claims 30-32 comply with the written description requirement under 35 U.S.C. §112, first paragraph.

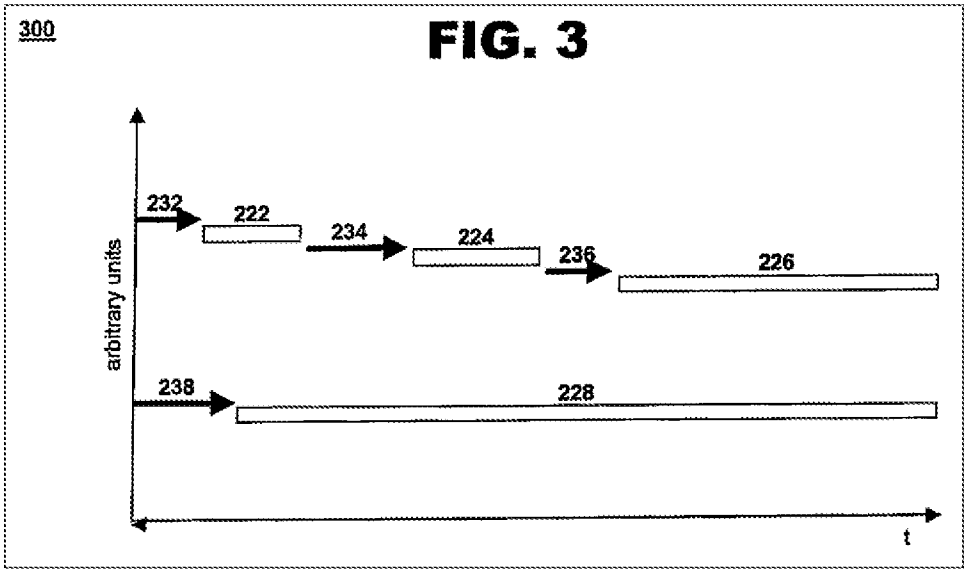
35 U.S.C. §112 Rejections

Claims 30-32 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, particularly, for not having a written basis for the new limitation that the plurality of therapeutic agents is released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded. The Appellant respectfully disagrees and asserts that the written description in the specification fully supports the limitation.

At least, the present Appellant's application recites that the timing coating is actuated when it begins to erode, and the second therapeutic agent is released after the timing coating has eroded. *See* paragraph [0038]. The timing coating is actuated when it begins to erode, and the third therapeutic agent is released after the timing coating has eroded. *See* paragraph [0040]. Further, Figure 3 clearly shows erosion of the timing coating 232, followed by release of therapeutic coating 222, erosion of the timing coating 234, followed by release of therapeutic coating 224, and erosion of the timing coating 236, followed by release of therapeutic coating 226. *See* Figure 3; paragraphs [0026]-[0033]. The erosion of the timing coating is only shown as occurring before the release of therapeutic coating, so the timing coating erodes completely before the next therapeutic coating is released.

On page 2 of the Advisory Action dated July 14, 2010, the Examiner asserted that, while the arrow symbols in this figure clearly translate to a time lag due to the presence of the timing coatings, it is not clear that they represent the complete or partial erosion of these layers. The Appellant respectfully disagrees.

As shown in Figure 3 of the Appellant's application, reproduced below, timing coating 232 is only present from the initial time until therapeutic coating 222 begins release. Timing coating 234 is only present from the time therapeutic coating 222 ceases release until therapeutic coating 224 begins release. Timing coating 236 is only present from the time therapeutic coating 224 ceases release until therapeutic coating 226 begins release. *See* paragraph [0026]. The arrow showing the action of each timing coating does not overlap the block showing the release of each therapeutic coating, so the adjacent overlying timing coating has completely eroded before the next therapeutic coating is released.



On page 2 of the Advisory Action dated July 14, 2010, the Examiner asserted that there is no statement or suggestion in paragraphs [0038] and [0040] that the timing coating must be completely gone before the release of therapeutic agent commences. The Appellant respectfully disagrees. Paragraphs [0038] and [0040] state that the therapeutic agent is released after the timing coating has eroded. *See* paragraphs [0038] and [0040]. This further supports the complete erosion for precise timed release as shown in Figure 3.

Thus, Figure 3 and paragraphs [0026]-[0033], as well as paragraph [0038] and [0040], provide the support required by the written description requirement.

Reversal of the rejection of claims 30-32 under 35 U.S.C. §112 as failing to comply with the written description requirement is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The Appellant respectfully asserts that the cited references fail to teach or suggest all the claim limitations, are not properly combinable, teach away from the claimed invention, and lack a motivation to combine.

A. Claims 12, 14, 15, and 18-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0153983 to Miller, *et al.* (the *Miller* publication) in view of U.S. Patent No. 6,471,980 to Sirhan, *et al.* (the *Sirhan C* patent).

The Appellant respectfully asserts that the *Miller* publication and the *Sirhan C* patent publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Appellant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Appellant asserts that the *Miller* publication and the *Sirhan C* patent fail to disclose, teach, or suggest:

> A coated stent wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12.

At most, the *Miller* publication discloses a medical device may comprise one or more layers comprising one or more distinct matrix polymer layers and, if desired, one or more barrier layers. *See* paragraph [0052]. A barrier layer can be provided to control the rate of release of bioactive material or therapeutic agent from an adjacent layer, such a matrix polymer layer. *See* paragraph [0055]. First and second barrier layers (also annular in shape) are disposed on the exterior and interior surfaces, respectively, of the first annular layer. The first and second barrier layers that enclose the first annular layer are typically less permeable than the biocompatible matrix polymer and, thereby, control the rate of diffusion of the bioactive and optional therapeutic agents from the device to the external environment. *See* paragraph [0056]. The bioactive and/or therapeutic agent from the annular layer comprising the first matrix polymer composition would have to diffuse through its own barrier layer, into and through an annular layer comprising the second matrix polymer composition and through another barrier layer before reaching the external environment. *See* paragraph [0062]. Thus, the barrier layers of the *Miller* publication allow diffusion of the therapeutic agents through the barrier layers and do not cause the therapeutic agents to be released exclusively and sequentially as claimed. A therapeutic agent from an inner layer will diffuse through the outer layers and mix with therapeutic agents from the outer layers, so that the inner and outer layer drugs are administered simultaneously rather than sequentially.

At most, the *Sirhan C* patent discloses means for releasing the substance comprises a reservoir on or within the structure containing mycophenolic acid and a cover over the reservoir. The cover may be degradable or partially degradable over a preselected time period so as to provide the desired mycophenolic acid release rate. *See* column 5, lines 57-62. Further, the *Sirhan C* patent discloses a rate limiting barrier may be formed adjacent to the structure and/or the matrix. Such rate limiting barriers may be nonerodible or nondegradable, such as silicone, polytetrafluorethylene (PTFE), parylene, and PARYLAST^{TM}, and control the flow rate of release passing through the rate limiting barrier. In such a case, mycophenolic acid may be released by diffusion through the rate limiting barrier. *See* column 5, lines 25-32. Although the *Sirhan C* patent suggests a combination of multiple drugs that are individually

included in different coats, where the coats may release the multiple drugs simultaneously and/or sequentially, the *Sirhan C* patent fails to disclose layers allowing each of the plurality of therapeutic coatings to be released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings as claimed.

On page 2 of the Advisory Action dated July 14, 2010, the Examiner asserted that Miller et al. explicitly envisioned biodegradable polymers in these barrier layers and that such a material would erode over time, so Miller et al. teaches that drugs are released by mechanisms other than diffusion through the barrier layers, thereby providing the same mechanism of delivery touted by applicants. The Appellants respectfully disagree. The disclosure of the *Miller* publication allows diffusion of the therapeutic agents through the barrier layers, which does not cause the therapeutic agents to be released exclusively and sequentially as claimed. *See* paragraph [0056], [0062].

The Examiner further asserted that Sirhan C teach a layered coating configuration with rate limiting barriers, which like the instant claims and Miller et al. are biodegradable, with such a configuration generating the sequential delivery of drugs from the layered system. The Appellants respectfully disagree. The *Sirhan C* patent discloses a reservoir on or within the structure containing mycophenolic acid and a cover over the reservoir. A nonerodible or nondegradable rate limiting barrier may be formed adjacent to the structure and/or the matrix. Mycophenolic acid may be released by diffusion through the rate limiting barrier. Thus, the mycophenolic acid and any therapeutic agent in a biodegradable cover over the reservoir are released simultaneously, not exclusively and sequentially as claimed. *See* column 5, lines 25-32, lines 57-62.

Claims 14, 15, and 18-20 depend directly or indirectly from independent claim 12, and so include all the elements and limitations of independent claim 12. The Appellant therefore respectfully submits that dependent claims 14, 15, and 18-20 are allowable over the *Miller* publication for at least the same reasons as set forth above for independent claim 12.

Regarding claims 18 and 20, the *Miller* publication and the *Sirhan C* patent fail to disclose a timing coating as claimed. At most, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer. *See* paragraph [0062]. At most, the *Sirhan C* patent discloses a cover over the reservoir and rate limiting barriers allowing diffusion. *See* column 5, lines 25-32, 57-62.

Reversal of the rejection of claims 12, 14, 15, and 18-20 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication is respectfully requested.

B. Claims 1-3, 7-12, and 19-29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2003/0033007 to Sirhan, *et al.* (the *Sirhan B* publication) in view of U.S. Patent Publication No. 2004/0002755 to Fischell, *et al.* (the *Fischell* publication).

The Appellant respectfully asserts that the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, and the *Fischell* publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Appellant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Appellant asserts that the *Miller* publication and the *Sirhan C* patent, alone or in combination, fail to disclose, teach, or suggest:

> A system for treating a vascular condition including therapeutic agents in each of the therapeutic coatings being released exclusively and sequentially upon the erosion of the overlying timing coating without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 1; or
>
> A coated stent wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent

to the ends of the stent, as recited in independent claim 12; or

A method of inhibiting restenosis adjacent to the ends of a stent used to treat a vascular condition including releasing the first therapeutic agent from the first therapeutic coating without releasing the second therapeutic agent from the second therapeutic coating, as recited in independent claim 23.

The *Sirhan B* publication and the *Fischell* publication also fail to disclose these limitations. At most, as discussed in Section A above, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer and the *Sirhan C* patent discloses a cover over the reservoir and rate limiting barriers allowing diffusion, but neither discloses sequential release of therapeutic agents as claimed.

Claims 2, 3, and 7-11; claims 19-22; and claims 24-29 depend directly or indirectly from independent claims 1, 12, and 23, respectively, and so include all the elements and limitations of their respective independent claims. The Appellant therefore respectfully submits that dependent claims 2, 3, 7-11, 19-22, and 24-29 are allowable over the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, and the *Fischell* publication for at least the same reasons as set forth above for their respective independent claims.

Regarding claims 7, 9, and 27, the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, and the *Fischell* publication fail to disclose a timing coating as claimed. At most, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer. *See* paragraph [0062]. At most, the *Sirhan C* patent discloses a cover over the reservoir and rate limiting barriers allowing diffusion. *See* column 5, lines 25-32, 57-62.

Reversal of the rejection of claims 1-3, 7-12, and 19-29 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, and the *Fischell* publication is respectfully requested.

C. Claims 12 and 31 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2004/0249449 to Shanley, *et al.* (the *Shanley* publication).

The Appellant respectfully asserts that the *Miller* publication, the *Sirhan C* patent, and the *Shanley* publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Appellant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Appellant asserts that the *Miller* publication and the *Sirhan C* patent, alone or in combination, fail to disclose, teach, or suggest:

> A coated stent wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12.

The *Shanley* publication also fails to disclose these limitations. At most, as discussed in Section A above, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer and the *Sirhan C* patent discloses a cover over the reservoir and rate limiting barriers allowing diffusion, but neither discloses sequential release of therapeutic agents as claimed.

Claim 31 depends directly from independent claim 12 and so includes all the elements and limitations of independent claim 12. The Appellant therefore respectfully submits that dependent claim 12 is allowable over the *Miller* publication, the *Sirhan C* publication, and the *Shanley* publication for at least the same reasons as set forth above for independent claim 12.

Regarding claim 31, the *Miller* publication, the *Sirhan C* publication, and the *Shanley* publication fail to disclose each of the plurality of therapeutic agents being released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely

eroded as claimed.

Reversal of the rejection of claims 12 and 31 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication, the *Sirhan C* publication, and the *Shanley* publication is respectfully requested.

D. Claims 1, 23, 30, and 32 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of the *Sirhan B* publication in view of the *Fischell* publication and further in view of the *Shanley* publication.

The Appellant respectfully asserts that the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, the *Fischell* publication, and the *Shanley* publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Appellant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Appellant asserts that the *Miller* publication and the *Sirhan C* patent, alone or in combination, fail to disclose, teach, or suggest:

> A coated stent wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12; or
>
> A method of inhibiting restenosis adjacent to the ends of a stent used to treat a vascular condition including releasing the first therapeutic agent from the first therapeutic coating without releasing the second therapeutic agent from the second therapeutic coating, as recited in independent claim 23.

The *Sirhan B* publication, the *Fischell* publication, and the *Shanley* publication also fail to disclose these limitations. At most, as discussed in Section A above, the *Miller* publication

discloses a barrier layer allowing diffusion through the barrier layer and the *Sirhan C* patent discloses a cover over the reservoir and rate limiting barriers allowing diffusion, but neither discloses sequential release of therapeutic agents as claimed.

Claims 30 and 32 depend directly from independent claims 1 and 23, respectively, and so include all the elements and limitations of their respective independent claims. The Appellant therefore respectfully submits that dependent claim 12 is allowable over the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, the *Fischell* publication, and the *Shanley* publication for at least the same reasons as set forth above for their respective independent claims.

Regarding claims 30 and 32, the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, the *Fischell* publication, and the *Shanley* publication fail to disclose each of the plurality of therapeutic agents being released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded as claimed.

Reversal of the rejection of claims 1, 23, 30, and 32 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, the *Fischell* publication, and the *Shanley* publication is respectfully requested.

8. SUMMARY

The Appellant respectfully submits that claims 1-3, 7-12, 14, 15, and 18-32 fully satisfy the requirements of 35 U.S.C. §103. In view of the foregoing, reversal of the rejection of claims 1-3, 7-12, 14, 15, and 18-32 is respectfully requested.

Respectfully submitted,

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9. CLAIMS APPENDIX

Claim 1 (previously presented): A system for treating a vascular condition, comprising:

a catheter; and

a coated stent operably coupled to the catheter, the coated stent including a plurality of therapeutic coatings disposed on a distal end and a proximal end of the stent and a plurality of timing coatings disposed on the distal and proximal ends of the stent, the timing coatings alternating with the therapeutic coatings, wherein each therapeutic coating comprises a bioerodable polymer and a therapeutic agent and wherein each timing coating comprises a bioerodable polymer, wherein each of the plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the therapeutic coatings being released exclusively and sequentially upon the erosion of the overlying timing coating without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent.

Claim 2 (original): The system of claim 1 wherein the therapeutic agents are selected from a group consisting of an antiproliferative agent, an antineoplastic agent, an antibiotic agent, an anti-inflammatory agent, a free radical scavenger, a protein, and combinations thereof.

Claim 3 (original): The system of claim 1 wherein the therapeutic agents are selected from a group consisting of paclitaxel, dexamethasone, rapamycin, a rapamycin analog, a nonsteroidal anti-inflammatory drug, a steroidal anti-inflammatory drug, a superoxide dismutase mimic, apo A-1 Milano, and combinations thereof.

Claims 4-6 (cancelled)

Claim 7 (previously presented): The system of claim 1 wherein each timing coating prevents release of the therapeutic agent from the therapeutic coating positioned beneath the timing coating until a predetermined time.

Claim 8 (previously presented): The system of claim 1 further comprising:

the coated stent including at least one therapeutic coating disposed on a longitudinal mid-portion of the stent.

Claim 9 (previously presented): The system of claim 8 further comprising:

at least one timing coating disposed on the longitudinal mid-portion of the stent.

Claim 10 (previously presented): The system of claim 8 wherein the therapeutic coating disposed on the longitudinal mid-portion of the stent releases a therapeutic agent that is different from the therapeutic agents released from the therapeutic coatings disposed on the distal and proximal ends of the stent.

Claim 11 (previously presented): The system of claim 8 wherein the therapeutic coating disposed on the longitudinal mid-portion of the stent displays diffusion characteristics that are different from those of the therapeutic coatings disposed on the distal and proximal ends of the stent.

Claim 12 (previously presented): A coated stent, comprising:

a stent framework;

a plurality of therapeutic coatings disposed on a distal end and a proximal end of the stent framework, each therapeutic coating comprising a bioerodable polymer and a therapeutic agent; and

a timing coatings disposed on the distal and proximal ends of the stent framework, the timing coatings alternating with the therapeutic coatings, each timing coating comprising a bioerodable polymer,

wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent.

Claim 13 (cancelled)

Claim 14 (original): The coated stent of claim 12 wherein the therapeutic agents are selected from a group consisting of an antiproliferative agent, an antineoplastic agent, an antibiotic agent, an anti-inflammatory agent, a free radical scavenger, a protein, and combinations thereof.

Claim 15 (original): The coated stent of claim 12 wherein the therapeutic agents are selected from a group consisting of paclitaxel, dexamethasone, rapamycin, a rapamycin analog, a nonsteroidal anti-inflammatory drug, a steroidal anti-inflammatory drug, a superoxide dismutase mimic, apo A-1 Milano, and combinations thereof.

Claims 16-17 (cancelled)

Claim 18 (previously presented): The coated stent of claim 12 wherein each timing coating prevents release of the therapeutic agent from the therapeutic coating positioned beneath the timing coating until a predetermined time.

Claim 19 (previously presented): The coated stent of claim 12 further comprising:

at least one therapeutic coating disposed on a longitudinal mid-portion of the stent framework.

Claim 20 (previously presented): The coated stent of claim 19 further comprising:

at least one timing coating disposed on the longitudinal mid-portion of the stent framework.

Claim 21 (previously presented): The coated stent of claim 19 wherein the therapeutic coating disposed on the longitudinal mid-portion of the stent releases a therapeutic agent that is different from the therapeutic agents released from the therapeutic coatings disposed on the distal and proximal ends of the stent.

Claim 22 (previously presented): The coated stent of claim 19 wherein the therapeutic coating disposed on the longitudinal mid-portion of the stent displays diffusion characteristics that are different from those of the therapeutic coatings disposed on the distal and proximal ends of the stent framework.

Claim 23 (previously presented): A method of inhibiting restenosis adjacent to the ends of a stent used to treat a vascular condition, comprising:

providing a coated stent, the coated stent including a first and a second therapeutic coating disposed on a distal and a proximal end of the stent, the first therapeutic coating including a bioerodable polymer and a first therapeutic agent, the second therapeutic coating including a second therapeutic agent, the coated stent further including a first timing coating positioned between the first and second therapeutic coatings, the timing coating comprising a bioerodable polymer;

deploying the coated stent in a vessel;

releasing the first therapeutic agent from the first therapeutic coating without releasing the second therapeutic agent from the second therapeutic coating;

eroding the bioerodable polymer of the first therapeutic coating;

actuating the first timing coating based on the eroding of the bioerodable polymer; and

releasing the second therapeutic agent from the second therapeutic coating at a time controlled by the first timing coating.

Claim 24 (original): The method of claim 23 wherein the therapeutic agents are selected from a group consisting of an antiproliferative agent, an antineoplastic agent, an antibiotic agent, an anti-inflammatory agent, a free radical scavenger, a protein, and combinations thereof.

Claim 25 (original): The method of claim 23 wherein the therapeutic agents are selected from a group consisting of paclitaxel, dexamethasone, rapamycin, a rapamycin analog, a nonsteroidal anti-inflammatory drug, a steroidal anti-inflammatory drug, a superoxide dismutase mimic, apo A-1 Milano, and combinations thereof.

Claim 26 (previously presented): The method of claim 23 further comprising:

releasing a third therapeutic agent from a third therapeutic coating, the third therapeutic agent disposed on a longitudinal mid-portion of the stent framework.

Claim 27 (previously presented): The method of claim 26 further comprising:

first actuating a second timing coating, the second timing coating disposed over the third therapeutic agent on the longitudinal mid-portion of the stent framework.

Claim 28 (original): The method of claim 23 wherein the second therapeutic agent is different from the first therapeutic agent.

Claim 29 (original): The method of claim 26 wherein the third therapeutic agent is different from the first and second therapeutic agents.

Claim 30 (previously presented): The system of claim 1 wherein each of the plurality of therapeutic agents is released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded.

Claim 31 (previously presented): The coated stent of claim 12 wherein each of the plurality of therapeutic agents is released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded.

Claim 32 (previously presented): The method of claim 23 wherein the releasing the second therapeutic agent from the second therapeutic coating comprises releasing the second therapeutic agent from the second therapeutic coating after the first timing coating has completely eroded.

10. EVIDENCE APPENDIX

None.

11. RELATED PROCEEDINGS APPENDIX

None.